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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/810,809

03/29/2004

Mirna Urquidi-MacDonald

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08/11/2006

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EXAMINER

SIMS, JASON M

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 08/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/810,809	Applicant(s) URQUIDI-MACDONALD ET AL.	
	Examiner Jason M. Sims	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) 20-46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/29/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's election with traverse of group I, claims 1-19, in the reply filed on 6/6/2006 is acknowledged. The traversal is on the ground(s) that the inventive groups are classified in the same class and that the searches for both groups will be overlapping in nature and therefore will not constitute a serious burden. This is not found persuasive because the related inventions are distinct if the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the different and distinct groups have different modes of operations, functions, and effects. For example, group I uses one neural network and group II uses two neural networks and a neural network to produce a second data set that is used to train the second neural network. Therefore, some common limitations are not persuasive as the invention as a whole is being evaluated for examination distinctness.

The requirement is still deemed proper and is therefore made FINAL.

Claims 20-46 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventive group, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 6/6/2006.

Claims 1-19 are the current claim set hereby under examination.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-19 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Under the Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility (published in the O.G. notice (1300 OG 142) on 11/22/2005) a method that does not result in a physical transformation of matter MAY be statutory where it recites a concrete, tangible and useful result; i.e. a practical application.

In the instant case, the claims are directed to a method of predicting a drug dose necessary to achieve a desired drug effect using patient clinical characteristics comprising inputting to a computer neural network a first data set comprising drug dose data, drug effect data, and patient characteristics, training the network, and using the network to predict a drug dose for a specific patient given a desired drug effect and patient characteristics. In the instant case, the method of claims 1-19 does not result in a physical transformation of matter, nor is any concrete, tangible and useful result produced/recited. Therefore, these claims are not statutory.

Claim Rejections - 35 USC § 102

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000.

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Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 3-6, 10-12, and 14-15, and 18-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Tang et al (US P/N 6,658,396).

The claims are directed to a method of predicting a drug dose necessary to achieve a desired drug effect using patient clinical characteristics comprising inputting to a computer neural network a first data set comprising drug dose data, drug effect data, and patient characteristics, training the network, and using the network to predict a drug dose for a specific patient given a desired drug effect and patient characteristics.

Tang et al teaches claim 1 at col. 1, lines 5-25, col. 5, lines 44-52, and col. 6, lines 13-31. Tang et al. at col. 1 discusses the construction, training, and usage of neural networks to optimize patient dosage and administration of patient drug with respect to patient characteristics. Tang et al. at col. 6 discusses using actual historical patient data for training the neural networks, which represents inputting into a computer a first data set comprising drug dose data, drug effect data, and patient characteristics data for a plurality of patients. Tang et al. at col. 5 discusses the use of an algorithmically-based, using a neural network, computerized, accurate optimization of drug dosage for an individual patient based on the patient data, which represents using the computer neural network to predict a drug dose for a specific patient given a desired drug effect and patient characteristics of the specific patient.

Tang et al. teaches claims 3 and 4 at col. 12, lines 60-63. Tang et al. discusses various algorithms that may be used for implementation and a standard one of those techniques being backpropagation, which is a steepest descent learning algorithm.

Tang et al. teaches claim 5 at col. 6, lines 13-67, col. 7-9, and col. 10, lines 1-35. Tang et al. discusses training a neural network by establishing a relationship between the drug dosage and drug effects, such as side effects, and patient characteristics, such as race, gender, and weight etc.

Tang et al. teaches claim 6 at col. 9, lines 5-40 and col. 10, lines 8-35. Tang et al. discusses using medical records from a large number of persons who have been administered the particular drug as input data and relating the selected input data to the output data. Tang et al. discusses using this data with patient characteristics to optimally select a drug dosage, which represents using drug dose data and patient characteristic data. Tang et al. also discusses the neural network architect and programmer select the neural network that best optimally relates the input to output data, which the optimization represents a method of adjusting a weight in the computer neural network based on a difference between predicted drug effect and received drug effect data.

Tang et al. teaches claims 10 and 11 at col. 6, lines 13-31. Tang et al. discusses the patient characteristics to be comprised of gender, ethnicity, age, height, weight, medical diagnostics, which is representative of the use of other drugs and other requirements for patient characteristics cited in claim 10.

Tang et al. teaches claims 12, 14-16, and 18-19 as applied to claims 1, 3-7, and 9-10 above and further at col. 27, lines 50-67 and col. 28, lines 1-59. Tang et al. discusses patient data being entered into spreadsheets and programming languages used to program the neural networks, which are stored and ran on computer-readable memory. Therefore, Tang et al. has taught the applications of the neural networks as stated above and discusses the computer language used to program the algorithmic applications, which represents a computer –readable medium having the instructions to perform the stated method steps.

Claim Rejections - 35 USC § 103

Claims 2 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tang et al (US P/N 6,658,396) as applied to claims 1, 3-6, 8, 10-12, 14-16, and 18-19 above, and further in view of Cohen et al. (US P/N 6,797,519).

Tang et al. does not specifically teach using a neural network to predict a drug dose for a particular patient for the drug abciximab.

Cohen et al teaches at col. 4, lines 1-5 and line 59-61, a workstation that retains a database of patient information, containing demographic data, medical history, treatment history, etc. and patient-related data, which may be communicated with an analysis tool. Additionally, Cohen et al. teaches a measuring method for creating patient data and patient related data, comprising data for anti-platelet agents such as abciximab.

Cohen et al. does not specifically teach applying a neural networking algorithm to the patient data for analysis for determining drug dosages, but Cohen et al. does teach

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applying the data to an algorithm for analysis and providing the treating physician with diagnostic and therapy options.

However, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine and apply the neural network applications taught by Tang et al. to the data about abciximab taught by Cohen et al. because there is a need for a method and apparatus for quickly and accurately analyzing data for providing the treating physician with diagnosis and therapy options.

Conclusion

No Claim is Allowed

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason Sims, whose telephone number is (571)-272-7540.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Andrew Wang can be reached via telephone (571)-272-0811.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (571)-273-8300.

Any inquire of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Yolanda Chadwick, whose telephone number is (571)-272-0514.

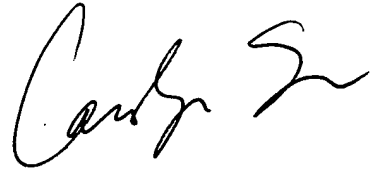
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "Carolyn S.", with a stylized, cursive script.

8/7/06 AU 1631 examiner